

**PS707: PHARMACOVIGILANCE (Open Elective - III)**

B.Pharm. IV Year I Sem.

L/T/P/C  
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**Course Objective:** This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection.

**Course Outcomes:** At completion of this paper it is expected that students will be able to (know, do, and appreciate):

- Why drug safety monitoring is important?
- History and development of pharmacovigilance
- National and international scenario of pharmacovigilance
- International standards for classification of diseases and drugs
- Adverse drug reaction reporting systems and communication in pharmacovigilance
- Data during pre-clinical, clinical and post approval.
- Pharmacovigilance Program of India (PvPI)
- ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning

**UNIT - I****10 Hours****Introduction to Pharmacovigilance:**

- a) History and development of Pharmacovigilance
- b) Importance of safety monitoring of Medicine
- c) WHO international drug monitoring programme
- d) Pharmacovigilance Program of India (PvPI)

**Introduction to adverse drug reactions:**

- a) Definitions and classification of ADRs
- b) Detection and reporting
- c) Methods in Causality assessment
- d) Severity and seriousness assessment
- e) Predictability and preventability assessment

**Basic terminologies used in pharmacovigilance:**

- a) Terminologies of adverse medication related events
- b) Regulatory terminologies

**UNIT – II****10 hours****Drug and disease classification:**

- a) Anatomical, therapeutic and chemical classification of drugs
- b) International classification of diseases
- c) Daily defined doses

**Drug dictionaries and coding in pharmacovigilance:**

- a) WHO adverse reaction terminologies
- b) MedDRA and Standardized MedDRA queries
- c) WHO drug dictionary

**Information resources in pharmacovigilance:**

- a) Basic drug information resources

**Establishing pharmacovigilance programme:**

- a) Establishing in a hospital
- b) Establishment & operation of drug safety department in industry
- c) Contract Research Organizations (CROs)

**UNIT – III**

**10 Hours**

**Vaccine safety surveillance:**

- a) Vaccine Pharmacovigilance
- b) Vaccination failure
- c) Adverse events following immunization

**Pharmacovigilance methods:**

- a) Passive surveillance – Spontaneous reports and case series
- b) Stimulated reporting
- c) Active surveillance – Sentinel sites, drug event monitoring and registries
- d) Comparative observational studies – Cross sectional study, case control study and cohort study
- e) Targeted clinical investigations

**UNIT – IV**

**08 Hours**

**Statistical methods for evaluating medication safety data**

**Safety data generation:**

- a) Pre-clinical phase
- b) Clinical phase
- c) Post approval phase

**ICH Guidelines for Pharmacovigilance:**

- a) Organization and objectives of ICH
- b) Expedited reporting
- c) Individual case safety reports
- d) Periodic safety update reports
- e) Post approval expedited reporting
- f) Pharmacovigilance planning
- g) Good clinical practice in pharmacovigilance studies

**UNIT – V**

**07 hours**

**Pharmacogenomics of adverse drug reactions:**

**Drug safety evaluation in special population**

- a) Pediatrics
- b) Pregnancy and lactation
- c) Geriatrics

**Recommended Books (Latest edition):**

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.

6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones& Bartlett Publishers.
7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
12. <http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297>
13. <http://www.ich.org/>
14. <http://www.cioms.ch/>
15. <http://cdsco.nic.in/>
16. [http://www.who.int/vaccine\\_safety/en/](http://www.who.int/vaccine_safety/en/)
17. [http://www.ipc.gov.in/PvPI/pv\\_home.html](http://www.ipc.gov.in/PvPI/pv_home.html)